

REMARKS/ARGUMENTS

A Final Office Action was mailed on May 23, 2006. Applicants mailed a responsive Amendment B on September 23, 2006. An Advisory Action was mailed on August 30, 2006. The Advisory Action indicated that Amendment B would be entered. The Advisory Action further indicated that the 35 USC §112 rejection of Claims 4 and 17 (in the Final Office Action) had been overcome, but that Claims 1-20 were still rejected. Thus, Claims 1-20 remain pending in this application. This Amendment C is being filed with an RCE in response to the Advisory Action. This amendment C currently amends Claims 1, 13, 14, and 18.

Claims 4 and 17 rejected under 35 U.S.C. §112, first paragraph

In the Final Office Action, Claims 4 and 17 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In response to the §112 rejection, in Amendment B, Applicants amended the claims 4 and 7 back to the form as originally filed. The Advisory Action indicated that this §112 rejection was removed.

Claims 1, 2, 5-11, 14, 17 and 18 rejected under §35 U.S.C. § 102(b)

In the Final Office Action, Claims 1, 2, 5-11, 14, 17 and 18 were rejected under 35 U.S.C. §102(b) as being anticipated by Williams et al. (U.S. Pat. No. 6,214,016, hereinafter referred to as “Williams”). The Advisory Action indicated that the rejection remained even after consideration of Applicants’ new arguments in Amendment B. The

Advisory Action noted [page 2, paragraph 1] that features relied upon by Applicants (i.e., a tube and inner core which are not movable in relation to each other) are not recited in the rejected claim(s).

In response, in this present Amendment C, Applicants have explicitly added into independent Claim 1 and Claim 14 the phrase, “wherein the outer covering and inner core are not movable with respect to each other”. Similarly, Applicants have explicitly added into independent Claim 18 a similar phrase, “ wherein the outer covering and inner core material are not movable with respect to each other”.

The addition of the phrase that the outer covering and inner core (or inner core material) are not movable with respect to each other overcomes the §102(b) rejection because this element is missing in Williams since Williams teaches movable parts. The outer tubular member 42, the inner tubular member 44, and the innermost member 46 (the stylet) are separate because they are “slidably movable within each other and are selectively positionable.” [See, Williams, column 6, lines 60-63, and also Figure 6.]

This feature of “slidably movable” between all parts is a key feature of the Williams invention. As explained throughout Williams’ specification, all of the elements must be movably slidable relative to each other (and therefore movably separate from each other) because Williams’ device permits the stylet to curve or bend through tissue such as brain tissue. [See Williams, column 3, lines 1-19.] Indeed, in order to achieve the purpose of the design to provide curved entry into tissue, e.g., the brain, Williams’s positioning device requires that all parts be movable with each other. “[T]he outer tubular member 42 has a greater rigidity than the inner tubular member 44, such that the outer tubular member 42 remains substantially linear when the inner tubular

member 44 is positioned substantially within the outer tubular member. [Williams, column 4, lines 52-57.] In addition, “[w]hen exiting the outer tubular member, the inner tubular member elastically resumes its curvature and advances outwardly along a curved path into and through the organ.” [Williams, column 3, lines 8-11]. The purpose of each of the parts, stylet 46, inner tubular member 44, outer tubular member 42 is to permit the inner tubular member 44 to curve as it extends out from the more rigid outer tubular member 42. The innermost member or stylet 46 [Williams, column 6, line 7] simply extends further from the inner tubular member 44, and causes the catheter or lead 50 to curve and extend out. [See Williams, Figures 4, 5 and 6.] Importantly, all parts are slidably movable with respect to each other, as they must in order for the lead or catheter to take a curved path.

Although Applicants' specification mentions [paragraphs 43 and 46] that a rod may be inserted into an outer covering, that does not mean, however, that the rod is movable with respect to the outer covering after the stylet is assembled or while the stylet is in use. There is no suggestion in Applicants' specification that the final assembled stylet has a movable inner core relative to the outer covering.

To the contrary, Applicants' stylet is intended to do the opposite -- the inner core is not movable with respect to outer covering while the stylet is in use. The specific purpose is to create a composite stylet having mechanical properties imparted by the outer covering and the inner core at the same time. [See Applicants' Specification, paragraphs 24, 29, 43 and 65 (second sentence).]

Applicants teach that the outer covering and inner core of the stylet are fixed relative to each other—not movable. The inner material may be a filling material

Appl. No. 10/635,091
Amendment C dated September 25, 2006
Reply to Advisory Action mailed August 30, 2006

Page 7 of 13

[Applicants' Specification, paragraph 46]. Such a filling is likely to be stuck inside the outer covering and unlikely to be movable. That would certainly be the case should the filling hardened inside the outer covering. [Applicants' Specification, paragraph 47, last sentence]. More telling, however, is the specific detailed instruction in Applicants' Specification on how a core is placed inside a nitinol tube and the nitinol tube is drawn over the core by pulling through a die. The drawn assembly is heated to a temperature above 400 degrees C for several minutes to set the nitinol over a core. [Applicants' Specification, paragraph 52.] "To set" means to make the core immovable relative to the outer covering. Hence, there is no description or rationale in Applicants' description of a composite stylet to make the inner core movable relative to the outer covering because that is not a goal of Applicants' stylet.

There is no discussion or rationale in Applicants' specification that the inner core is movable from the outer covering once the stylet is assembled. While it is true that Applicants' specification mentions that the inner core may be inserted into the outer covering, this merely describes a process of manufacturing the stylet having an inner core and outer covering. It does not mean that the inner core is slidably movable relative to the outer covering.

Applicants contend that Williams does not anticipate Applicants' independent Claims 1, 14 and 18 (and all dependent claims) because Applicants' claims now explicitly recite, wherein the outer covering and inner core (or inner core material) are not movable with respect to each other.

Claims 2 and 5-11 are dependent on Claim 1. Although there may be other reasons why Williams does not anticipate these dependent Claims 2 and 5-11, they are at least allowable because they depend on Claim 1, which is allowable.

Claim 17 is not anticipated, at least, although not necessarily only because of, its dependency on Claim 14.

Claim 13 rejected under 35 U.S.C. §102(b) or §103(a)

Claim 13 was rejected under 35 U.S.C. §102(b) as anticipated by Williams or alternatively §103(a) as obvious over Williams.

Applicants believe that the §102(b) anticipation argument has been overcome by amending independent Claim 1 by adding the phrase, “wherein the outer covering and inner core are not movable with respect to each other”. Williams is missing this element. Claim 13 depends from Claim 1 and, by this dependency, is not anticipated by Williams.

With respect to the §103(a) obviousness rejection, it is believed that the teachings of Williams suggest movable, slidably parts, and therefore teach away from Applicants Claim 1 and Claim 13, which teach immovable parts. As such, it is believed that an obviousness rejection based on Williams is overcome by the amendment made to Claim 1.

The Examiner has interpreted that the term “pre-stressed” to mean that an element will assume a straight configuration, and when the stress-applicator is removed, the element assumes a curve configuration. To clarify, Applicants have

Appl. No. 10/635,091
Amendment C dated September 25, 2006
Reply to Advisory Action mailed August 30, 2006

Page 9 of 13

amended Claim 13 by including, “so that the inner core operates on the compression side of the stress-strain curve”.

Claim 3, 4, and 12 rejected under 35 U.S.C. §103(a)

Claims 3, 4, and 12 were rejected under 35 U.S.C. §103(a) as unpatentable over Williams. Claims 3, 4 and 12 are all dependent on independent Claim 1, which is believed to be in condition for allowance after explicitly adding the phrase, “wherein the outer covering and inner core are not movable with respect to each other”. For that reason alone, although not necessarily the only reason, Claims 3, 4, and 12 are believed to be allowable.

Claim 15, 19, and 20 rejected under 35 U.S.C. §103(a)

Claims 15, 19 and 20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Williams in view of Stoy et. al. (U.S. 5,217, 026, hereinafter referred to as “Stoy”). Applicants’ Claim 15 depends from independent Claim 14, and Claims 19 and 20 depend from independent Claim 18. Williams does not make obvious independent Claims 14 and 18 because Williams teaches the use of a positioning device having multiple parts that are slidably movable relative to each other. Claims 14 and 18 describe, instead, a stylet that is a composite of an outer covering and inner core which are fixed relative to each other.

Stoy does not disclose a stylet having an outer covering that is metal. The outer covering is taught to be hydrogel. [See Stoy, abstract, and Claims 1-31.] The Examiner indicated in the Advisory Action that the proper test for obviousness is “what the combined teachings of the references would have suggested to those ordinary skilled in the art.” Applying such a test, one of ordinary skilled in the art would not combine the two references and, even if combined, it is uncertain that Applicants’ invention would result.

One of ordinary skilled in the art would have no reason to combine the Stoy and Williams references. The purposes and functionality of each device described in Williams and Stoy are very different. Williams uses slidable moving elements that are not fixed relative to each other to provide a curved path through tissue. Stoy teaches a stylet with an outer covering of hydrogels to have a lubricious coating surface to avoid stylet or guidewire sticking. Separate movable elements are important in Williams. Apparently, there are no movable elements in Stoy and the outer covering is fixed or integral to the inner core [Stoy, column 4, line 5]. The two devices are conflicting in their function and their teaching and one skilled in the art would have little reason to combine the two references.

But even if combined, Stoy and Williams do not readily yield Applicants’ Claims 15, 19 or 20 as they now include immovable outer covering and inner core, neither of which parts in Applicants’ invention are hydrogels. Stoy suggests that the outer covering is not a metal but a hydrogel and the inner core material is a metal or sometimes a ceramic. Williams, suggests that the outer covering is a metal, but the inner core is also a metal and they must be movable with respect to each other. These

references appear to contradict, not complement each other. Neither Stoy and Williams, by themselves, discloses both an (1) an outer metal covering and (2) a non-metal inner core – which is Claim 15. In addition, the specific inner core material of “magnesia partially stabilized Zirconia, Yttria stabilized Zirconia, ceramic, epoxy and hard polyurethane, is not disclosed by Williams, although a ceramic inner core is disclosed by Stoy. Claim 15 also includes “the outer covering material is selected from the group consisting of cold drawn 304 stainless steel, 316 stainless steel, 316L stainless steel and nitinol (425 nickel-titanium)”. Such a specific combination of outer metal covering with a non-metallic inner core material, as recited specifically in Applicants’ Claim 15, cannot be arrived at except by engaging in impermissible hindsight reconstruction.

Hence, (a) one of ordinary skilled in the art would have no reason to combine Stoy and Williams since the devices described in each serve completely different purposes. In addition, (b) one of ordinary skilled in the art combining Stoy and Williams to yield a metal outer covering with a non-metallic core must pick, for some reason, a non-metallic core from Stoy and metallic outer covering from Williams, in spite of the fact that Stoy specifically teaches that a hydrogel exterior is employed in conjunction with an inner core, and Williams specifically teaches parts that are movable with respect to each other. After amendments to Claims 14 and 18, dependent Claims 15, 19 and 20 now specifically include the element that the outer covering and inner core or inner core material are not movable with respect to each other. For the above reasons, the §103(a) obviousness rejection to Claims 15, 19 and 20 is believed to be overcome.

A REQUEST FOR CONTINUED EXAMINATION (RCE) IS SUBMITTED AND A ONE-MONTH EXTENSION OF TIME IS REQUESTED

With this Amendment C, a request for continued examination (RCE) is being submitted. A one-month extension of time is requested, making the due date for response to the Final Office Action (mailed May 23, 2006), September 25, 2006. Please charge the fee for this one-month extension, the fee for an RCE, and any other required fees to **Deposit Account Number 50-0648.**

An early indication of allowability of pending Claims 1-20 is courteously requested. The Examiner is encouraged to telephone the undersigned to resolve any issues concerning this application.

Respectfully Submitted,

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Date

/PhilipHLee/
Philip H. Lee
Reg. No. 50,645
Attorney for Applicants

Please direct all written inquiries to:
Bryant R. Gold
Advanced Bionics Corporation
25129 Rye Canyon Road
Valencia, California 91355
Fax: (661) 362-1507

Please direct all telephone inquiries to:
Philip H. Lee
Telephone: (661) 362-1964